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Gijsbertus Johannes Van Oorschot

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UNILEVER PATENT GROUP  
800 SYLVAN AVENUE  
AG West S. Wing  
ENGLEWOOD CLIFFS, NJ 07632-3100

EXAMINER

SULLIVAN, DANIELLE D

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/072,570  
Filing Date: February 08, 2002  
Appellant(s): VAN OORSCHOT ET AL.

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Michael P. Aronson  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 4/17/2009 appealing from the Office action mailed 11/25/2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

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**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

Manzoni, M. "Production of statins by filamentous fungi" Biotechnology Letters, Vol. 21, 1999, pp. 253-257

6,046,022	Zhang	4-2000
5,670,632	Chaihorsky	9-1997
4,218,489	Zilliken	8-1980

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 19-21, 23, 24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632).

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### **Applicant's Invention**

Applicant claims a food product selected from the group consisting of a margarine, a dressing, a sweet, a cereal bar, a breakfast cereal and a beverage; said food product comprising an extract of a fermentation product formed by fermenting a substrate comprising more than 50% by weight of soy ingredients (preferable 80%) with a statins producing monascus ruber fungus, wherein the fermentation product comprises one or more statins and one or more polyphenols and has a Hue a\* value less than 20; wherein said soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes; and wherein said extract is an ethanol extract or an edible oil extract (preferably more than 10% of a vegetable oil).

The fact that the fermentation product comprises statins and one or more polyphenols (comprising genistein and genistin) and has a Hue a\* value less than 20 is treated as an inherent property of the soybean fermentation product (includes polyunsaturated fatty acids, phytosterols, proteins, peptides, dietary fibers and saponins) when Monascus ruber fungus is used. Therefore, for the purpose of examination, the fermentation product is treated as the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients with a statins producing monascus ruber fungus.

### **Determination of the scope and the content of the prior art**

**(MPEP 2141.01)**

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Manzoni et al. teach a method of screening *Monascus* and *Aspergillus* strains for statins production (abstract). The medium contained 3% whole or defatted soybean flour (page 254, column 1, paragraph 3). Statins could then be isolated by extraction with ethyl acetate (page, 254, column 1, paragraph 5). Once the quantitative assay procedure was established, fermentation experiments using strains of *Monascus* and *Aspergillus* were carried out and the whole soybean flour had a 40-41% protein and 22-24% lipid content, while the defatted flour 49-52% proteins and only 0.5%-1.5% lipid content (page 255, column 1, paragraph 2). Results show that the lipid content of the media influenced statin biosynthesis (page 257, column 1, paragraph 1). The amount of statins produced was affected by strain used and duration of fermentation (See Table 1). Manzoni et al. teach that statins decrease cholesterol (page 253, column 2, paragraph 2).

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

Manzoni et al. do not teach a process of making a food product comprising an extract of the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients. However, in view of In re Aller, Lacey and Hall, 105 USPQ 233 (C.C.P.A. 1955), it is normal practice to change concentration to increase the degree of results obtained. Therefore, increase in the amount of soybean flour would increase statins production. Hence, one would have been motivated to manipulate ranges during routine experimentation to discover the optimum or workable range since

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Manzoni et al. provides the general range. Therefore, one would have been motivated to use the appropriate amount of soy ingredients.

Manzoni et al. also do not teach that the process is used in the formulation of a food product. It is for this reason that Zhang et al. is joined.

Zhang et al. teach a method of fermenting red rice with *Monascus* in order to formulate a dietary supplement or medicament for the treatment of high cholesterol in humans (column 4, lines 5-18). *Monascus ruber* is taught as a possible strain used in the fermentation process (column 4, lines 61-65). Zhang et al. teach that soybeans may be fermented by the process in order to obtain a nitrogen source in the food product (column 7, lines 5-20).

Manzoni et al. do not teach that the extract is an ethanol or edible oil. It is for this reason that Chaihorsky et al. is joined.

Chaihorsky et al. teach that isoflavones have been isolated from soybean plants for use as dietary supplements and include isoflavones in a glucone form, such as, genistein and genistin (column 1, lines 14-23). Typically, the isoflavones are eluted by a polar solvent such as methanol or ethanol (column 1, lines 60 and 61).

### **Finding of prima facie obviousness**

#### **Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al., Zhang et al. and Chaihorsky et al. to further include extracting the fermentation product with ethanol for a food product.

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One would have been motivated to include ethanol because it is used to concentrate isoflavones from soybeans. Therefore, using ethanol would isolate the isoflavones from the fermentation product for incorporation into a food product.

Claims 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632) in further view of Zilliken (US 4,218,489).

### **Applicant's Invention**

Applicant claims the product addressed in above 35 U.S.C. 103(a) rejection wherein the extract is an edible oil extract (preferably more than 10% of a vegetable oil).

### **Determination of the scope and the content of the prior art**

#### **(MPEP 2141.01)**

Manzoni et al., Zhang et al., and Chaihorsky as addressed in above 35 U.S.C. 103(a) rejection.

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

Manzoni et al., Zhang et al., and Chaihorsky do not teach an extract of an edible vegetable oil containing soy ingredients. It is for this reason that Zilliken is joined.



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Zilliken teach antioxidant food composition with isoflavones (abstract). Zilliken teaches that isoflavones or their extracts protect oils from oxidation (column 7, lines 46-51). Zilliken teaches a composition comprising stabilized edible oil (vegetable) and an antioxidant composition comprising 0.001-1% genistein (column 6, line 57 thru column 7 line 11).

### **Finding of prima facie obviousness**

#### **Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al., Zhang et al., Chaihorsky et al. and Zilliken to further include a food product comprising soy ingredients and vegetable oil. One of ordinary skill would have been motivated to obtain a food product comprising soy ingredients (genistein) and vegetable oil because Zilliken teach that such foods are known to have reduced oxidation and thus maintain freshness.

#### **(10) Response to Argument**

Appellants argue that the combination of Manzoni et al., Zhang et al. and Chaihorsky taken as a whole would not have suggested appellant's invention. First, Appellant argues that there is no evidence in Manzoni et al. to suggest that *M. ruber* produced any level of statins and one of ordinary skill would have been dissuaded from selecting it. The Examiner disagrees with this argument because Manzoni et al. teach that lovastatin is obtained from *M. ruber* (page 253, paragraph 2).

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Second, Appellant argues that there is no suggestion in Manzoni et al. to use more than 50% by weight of soy ingredients. However, in view of In re Aller, Lacey and Hall, 105 USPQ 233 (C.C.P.A. 1955), it is normal practice to change concentration to increase the degree of results obtained. Hence increasing the soy ingredients would inherently increase the amount of statins present in the fermentation product.

Third, Appellant argues that Chaihorsky is directed to extraction and purification of chemicals directly from soy plants not the fermentation products of soybeans. Appellants argue that this fermentation changes the composition. This argument is not persuasive because the fermentation product is composed of the same matter, soy. Furthermore, the claims are drawn to a food product, not the process of making the food product.

Appellants argue that Zhang et al. teach a dietary supplement or medicament not a food as recited in appellants' claims. The Examiner disagrees with this argument. Zhang et al. teach that the term "dietary supplement", means an additional element that is added to the daily food intake of a mammal (column 6, lines 4-6). The supplements may be incorporated into natural or processed foods, including syrups (sweets) thus constituting a food product (column 11, lines 27-63).

Appellants argue that the combination of Manzoni et al., Zhang et al., Chaihorsky and Zilliken, taken as a whole, would not have suggested appellant's invention. Appellants argue that there is not suggestion in Zilliken to utilize vegetable oil as an extraction medium. While the Examiner notes that vegetable oil is not disclosed as an extraction medium, it is noted that the claims are drawn to a composition comprising

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fermented soy and an edible oil, not a process of extraction. (Hence, in order to show prima facie obviousness one must provide a motivation for combining the edible oil to meet the claim limitations. Zilliken teaches fermented soybean possesses antioxidant properties and stabilize oils, including vegetable oil, and is used to protect against oxidation in food products (column 1, lines 46-50; column 2, lines 60-64; column 7, lines 46-55). Since Zilliken teaches soy food products containing vegetable oil and genistein are known to be stable, it would have been obvious to include vegetable oil in a soybean food product because the combination results in a stabilized food product.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

Conferees:

/Danielle Sullivan/

Examiner, Art Unit 1616

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617

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